Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

[UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendant.	No. ___ - _____ **COMPLAINT FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **Jury Trial Demanded**

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA and the States of ARKANSAS, CALIFORNIA, DELAWARE, FLORIDA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, TENNESSEE, TEXAS, UTAH, and VIRGINIA, and the DISTRICT OF COLUMBIA *EX REL* ROBERT GLUCK, M.D., Plaintiffs, v. BOSTWICK LABORATORIES, INC., Defendant.	No. ___ - _____ **COMPLAINT FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **Jury Trial Demanded**

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Relator Robert Gluck, M.D. ("Relator" or "Dr. Gluck"), on behalf of the United States of America and on behalf of the sovereign states of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, New York, Tennessee, Texas and Virginia and the District of Columbia (the "Certain States"), pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C.§§3729-3733 (the "FCA"), and the false claims acts of the Certain States (the "state false claims acts"), files this Complaint against Defendant Bostwick Laboratories, Inc. ("Bostwick" or "Defendant") and alleges as follows:

INTRODUCTION

1. Realtor brings this action to recover treble damages and civil penalties on behalf of the United States of America and Certain States, arising from false or fraudulent claims for laboratory testing reimbursements that were caused to be submitted by Defendant to Federal Government-funded programs including, without limitation, Medicaid, Medicare, the Federal Employees Health Benefits Program ("FEHBP") and TRICARE/CHAMPUS, in violation of the FCA.

2. Defendant has violated and continues to violate federal anti-kickback and related statutes by routinely paying kickbacks to physicians in order to induce those physicians to utilize Bostwick laboratory testing services, including laboratory testing services that are part of purported clinical trials and that are not medically necessary. Among other things, and as detailed more fully below, Defendant continues to engage in a blatant kickback scheme whereby Defendant pays physicians hundreds of dollars *per patient* when those physicians send patients' specimens to Defendant for laboratory testing and analyses. Defendant thinly disguises these kickbacks as compensation for participation as investigators in clinical trials, whereas in reality Defendant's cash payments to physicians are simply unlawful payments to physicians who steer laboratory testing business to Defendant.

3. The state false claims acts are modeled after the FCA and seek to prevent similar harms to state treasuries. *See* the Arkansas Medicaid Fraud Claims Act, Ark. Code Ann. §20-77-901; the California False Claims Act, Cal. Gov't Code §§ 12650-12655; the Delaware False Claims Act, Del. Code Ann.tit.6, § 1201, *et seq.*; the Florida False Claims Act, Fla.Stat.Ann. § 68.081, *et seq.*; the Hawaii False Claims Act, Haw.Rev. Stat. § 661-22, *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 III. Comp. Stat. 175/1, *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Ind. Code 5-11-5.5; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann § 45:439.1, *et seq.*; the Massachusetts False Claims Act, Nev. Rev. Stat. § 357.010, *et seq.*; the New Hampshire Medicaid Fraud and False Claims Law, N.H.Rev. Stat. Ann. § 167:61, *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat.Ann. §27-14-1, *et seq.*; the New York False Claims Act., N.Y. Stat. Ann. Ch. 56, Art. XIII, § 187, *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.*; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001, *et seq.*; the Utah False Claims Act, Utah Code Ann. § 26-20, *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1, *et seq.*; and the District of Columbia False Claims Act, D.C. Code § 2-308.03, *et seq.*

4. The illegal kickbacks paid by Defendant involved payments to physicians in return for those physicians sending patients' specimens to Defendant for laboratory testing services. In addition, Defendant paid physicians to collect additional, non-medically-necessary specimens from patients and then send those specimens to Defendant so that Defendant could run a purported clinical trial of its purportedly new laboratory tests. On information and belief, Defendant improperly submitted bills for reimbursement for its purported clinical trial to Government payors.

5. Defendant's illegal remuneration to physicians induced them to use Defendant's laboratory testing services. By paying illegal kickbacks to physicians which are not disclosed to the

Government, a violation of 42 U.S.C. § 1320a-7b(b) (the "Medicare Fraud & Abuse/Anti-Kickback Statue"), Defendant caused false or fraudulent claims to be filed by Defendant itself for reimbursement for Defendant's laboratory testing services from Federal Government-funded health programs. Defendant's conduct, as such, violated the FCA and the state false claims acts.

6. Defendant's unlawful kickback scheme illegally increased its market share for its services by inducing physicians to send specimens to Defendant for laboratory testing services that physicians otherwise would not have sent to Defendant or would not have ordered from anyone but for the receipt of the kickbacks and/or other illegal efforts. Further, Defendant's unlawful scheme caused false, fraudulent and improper billings to be made to Medicare, Medicaid, and other Government-funded health programs. The Federal Government and the Certain States consequently paid enormous sums for reimbursement claims they would have rejected had they been aware of Defendant's illegal actions. As a result of Defendant's illegal kickbacks and fraudulent clinical trial scheme, the public over utilized Defendant's laboratory testing services, the Federal Government's and Certain States' expenditures on laboratory testing services rose unnecessarily, and, in turn, Defendant reaped illegal profits.

7. Defendant has engaged in its wrongful conduct since 2008, or earlier, and Defendant's wrongful conduct is continuing.

8. Defendant concealed its unlawful conduct by, among other actions, failing to disclose that it was engaged in the unlawful conduct of kickbacks to physicians, resulting in violations of the Stark and Anti-Kickback laws, and seeking improper reimbursements for purported clinical trials.

9. By this action, Relator seeks to recover on behalf of himself and the United States of American and Certain States damages and civil penalties arising from the false or fraudulent claims that Defendant submitted or caused to be submitted to Government-funded health programs.

JURISDICTION AND VENUE

10. Relator brings this action on behalf of himself and on behalf of the United States of America and the Certain States for violations of the FCA, 31 U.S.C. §§ 3729-3733, for violations of the state false claims act. *See also* the Food, Drug and Cosmetics Act, 21 U.S.C. §301 *et seq.*; the Food and Drug Administration and Modernization Act of 1997, 21 U.S.C. § 351 *et seq.* and 21 U.S.C. § 360aaa *et seq.*; the Medicare/Medicaid Fraud & Abuse Anti-Kickback Statue, 42 U.S.C. § 1320a *et seq.*; and the Medicaid Rebate Statute, 42 U.S.C.§ 1396r-8.

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and 31 U.S.C. § 3732(a), which specifically confers this Court with jurisdiction over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court also has subject matter jurisdiction over the counts relating to the state false claims acts pursuant to 31 U.S.C. § 3732(b), as well as supplemental jurisdiction over the counts relating to the state false claims acts pursuant to 28 U.S.C. § 1367.

12. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because acts prohibited by 31 U.S.C. § 3729 occurred in the State of New York within this judicial district. Section 3732(a) authorizes nationwide service of process. *Id.*

13. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because at least one act proscribed by 31 U.S.C. § 3729 occurred in this District and because Defendant maintains facilities in this District in Uniondale, NY.

14. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint has been filed under seal and will remain under seal for a period of at least 60 days from its filing date, and shall not be served upon the Defendant until the Court so orders.

15. Pursuant to 31 U.S.C. § 3730(b)(2), prior to filing this Complaint Relator has provided the Government with a written disclosure of substantially all material evidence and material information in his possession. Relator has served copies of this Complaint on Benton J. Campbell, United States Attorney for the Eastern District of New York, and Eric H. Holder, Jr., United States Attorney General.

16. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil or administrative hearing, lawsuit or investigation; in a Government Accountability Office or Auditor General's report, hearing, audit, investigation, from the news media; or in any other location as the term "publicly disclosed" is defined in 31 U.S.C. § 3730(3)(4)(A).

17. To the extend that there has been a public disclosure of the information upon which the allegations of this Complaint are based that is unknown to Relator, Relator is an original source of this information as defined in 31 U.S.C. § 3730(e)(4)(B). Relator possesses direct and independent knowledge of the information, which he acquired in the course of his practice as a practicing urologist, during which time we was repeatedly contacted by Defendant concerning the conduct described herein. Relator voluntarily provided the Government with this information prior to filing this action. *See* 31 U.S.C. § 3730(e)(4).

PARTIES

18. Relator, Robert Gluck, resides in the state of New York and is a licensed, practicing urologist. Relator has direct and independent personal knowledge of Defendant's practices as a result of his work as a practicing urologist who was contacted by Defendant on numerous occasions concerning Defendant's unlawful kickback and clinical trial schemes.

19. Defendant Bostwick Laboratories, Inc. is full-service laboratory services company specializing in uropathology (the diagnosis, treatment and subsequent management of prostate

cancer, kidney disease, cancer of the bladder and other urologic conditions). Bostwick Laboratories, Inc. operates laboratories in Uniondale, NY, Richmond, VA, Orlando, FL, Nashville, TN and Tempe, AZ. Bostwick Laboratories, Inc.'s headquarters and corporate offices are located at 4355 Innslake Drive, Glen Allen, VA 23060. Bostwick Scientific is the clinical trials unit of Bostwick Laboratories, Inc. Bostwick Scientific provides scientific testing for clinical research. Bostwick Scientific is also located at 4355 Innslake Drive, Glen Allen, VA 23060.

20. The Federal and state governments, through their Medicaid and Medicare programs, among others, are among the principal purchasers of Defendant's services.

BACKGROUND

A. The False Claims Act.

21. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act.[1] The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States.

22. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1)-(2). The Act empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action. *Id.*

23. Payment of kickbacks to physicians to induce them to utilize laboratory testing services or order unnecessary tests for purported clinical trials, by a person who seeks reimbursement from a

[1] Amendments in 2009 further strengthened the FCA.

Federal Government-funded health program for laboratory testing services, or who causes another to do so, while certifying or impliedly certifying compliance with the Medicare Fraud & Abuse/Anti-Kickback Statute, the Medicaid Rebate Statute and the Food, Drug and Cosmetics Act, or while causing another to do so, constitutes a violation of the FCA.

B. Federal Government Health Programs

24. Medicare is a Federal Government health program primarily benefiting the elderly that Congress created in 1964 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicaid Services ("CMS"). Medicare will pay for most, though not all, laboratory testing services. Services that are not covered are billed to the patient.

25. Congress created Medicaid at the same time it created Medicare in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses to low-income patients. Funding for Medicaid is shared between the Federal Government and those state governments choosing to participate in the program. The Federal Government also separately matches certain state expenses incurred administering the Medicaid program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid usually provides more expansive coverage than Medicare. Like Medicare, most Medicaid plans will pay for most, though not all, laboratory testing services.

26. TRICARE is the health care system of the United State military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care

providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers.

27. The FEHBP provides health insurance coverage for nearly 8.7 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management.

C. The Medicare Fraud & Abuse/Anti-Kickback Statute

28. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320(a)-7(b)(b) (the "Anti-Kickback Statute"), which also covers Medicaid, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by fines of up to $25,000 and imprisonment for up to five years.

29. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals or business orders, including laboratory testing services, or that takes into account the volume or value of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f). Such remuneration amounts to a kickback when it is paid to induce or reward order flow by physicians for laboratory testing services. Kickbacks are harmful to public policy because they increase expenditures paid by the Government-funded health benefit programs by inducing medically unnecessary overutilization of laboratory testing services and excessive reimbursements. Such kickbacks also reduce a patient's healthcare

choices and cause physicians to steer their patients towards certain laboratories based on the physician's own financial interests rather than the patient's medical needs.

30. The Medicare Anti-Kickback Statute contains eight statutory exceptions from its statutory prohibitions, and certain regulatory "safe harbors" have been promulgated to exclude certain types of conduct from the reach of the statutes. *See* 42 U.S.C. § 1320a-7(b)(3). None of the statutory exceptions or regulatory safe harbors protects Defendant's conduct in this case.

31. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorize the exclusion of an individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party violated the Medicare Anti-Kickback Statute. The administrative sanction is $50,000 for each act and an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(7)

32. As detailed below, Defendant's payment and purported clinical trial scheme repeatedly violated and continues to violate provisions of the Anti-Kickback Statute, which in turn violates the FCA because Defendant's improper kickbacks and incentives induced physicians to order laboratory testing services from Defendant when they otherwise would not have, and many of those laboratory testing services were paid by Medicaid and other Government-funded health insurance programs.

D. Stark Law – The Medicare/Medicaid Self-Referral Statute

33. The Medicare/Medicaid Self-Referral Statute is commonly known as the "Stark" law. It prohibits Defendant from paying remuneration to physicians for referring Medicaid patients to Defendant for certain "designated health service," including laboratory testing services. 42 U.S.C. § 1395nn(a)(1), (h)(6). The Stark law provides that Defendant shall not cause to be presented a

Medicaid claim for such services. Stark also prohibits payment of Medicaid funds for services rendered in violation of its provisions. 42 U.S.C. § 1395nn(a)(1), (g)(1).

34. As detailed below, Defendant's unlawful kickback and clinical trial schemes repeatedly violated and continue to violate the provisions of the Stark law, which in turn violates the FCA because Defendant's improper payments to physicians induced those physicians to utilize and over-utilize Defendant's laboratory testing services when they otherwise would not have, and many of those services were paid for by Medicaid and other Government-funded health insurance programs.

E. Reimbursements for Clinical Trials

35. Medicare does not cover all costs associated with clinical trials. Among other rules and regulations, in certain circumstances, Medicare will cover the "routine costs" of qualifying clinical trials. National Coverage Determination ("NCD") for Routine Costs in Clinical Trials (310.1) (implemented on October 9, 2007), *available at* http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=310.1&ncd_version=2&basket=ncd%3A310%2E1%3A2%3ARoutine+Costs+in+Clinical+Trials .

36. According to the Medicare NCD, "routine costs" do not include:

(a) The investigational item or service, itself unless otherwise covered outside of the clinical trial;

(b) Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

(c) Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial

37. Upon information and belief, other Government payors make coverage determinations based on Medicare coverage determinations, and clinical trial costs not covered by Medicare generally are not covered by these other payors.

38. As detailed further below, Defendant's clinical trials scheme failed to comport with many of the provisions required for Medicare reimbursement, yet Defendant nonetheless submitted claims for reimbursement for its purported clinical trials to Government payor. Each of those claims are violations of the FCA.

SUBSTANTIVE ALLEGATIONS

A. Defendant's Laboratory Testing Services

39. Defendant provides laboratory testing services used in the diagnosis of certain forms of cancer, including prostate cancer and cancer of the bladder, as well as kidney disease and other urologic conditions.

40. Defendant styles itself as "the laboratory of choice for second opinions[, and] now the laboratory of choice for primary interpretations of prostate, bladder and kidney biopsies."

41. In addition to laboratory testing services, Defendant claims that it is "actively involved in clinical and basic research, continuing medical education of our pathology colleagues and patient education."

42. Defendant also claims that its Bostwick Scientific division "partners with biotech and pharmaceutical companies and physician investigators to provide reliable, comprehensive, and timely testing and reporting of study materials."

43. While Defendant attempts to differentiate itself, in reality its laboratory testing services are commodity products in which one would normally expect competition primarily on price.

44. Because of the tripartite nature of the heath care system, and specific the separation of the drivers of demand (i.e., the physicians) from the payors (e.g., government and private insurance), Bostwick decided to "compete" in this market not by offering lower prices to the payors, but rather by offering unlawful inducements to physicians.

45. Defendant's business depends on physicians, primarily urologists, sending patient specimens to Defendant for laboratory testing services. Defendant took the unlawful step of offering payments to physicians to drive and create demand.

46. Defendant was well aware of the tripartite market dynamics, and sought to take advantage of it by offering cash inducements to physicians to drive laboratory testing services business – much of it not medically necessary – to itself.

B. Defendant's Kickback Scheme to Drive Market Share and Seek Unlawful Reimbursement for Purported Clinical Trials.

1. Kickbacks for PCA3*Plus* Purported Clinical Trial

47. In 2008, or earlier, the exact date being unknown to Relator, Defendant began offering payments to physicians to utilize and over-utilize Defendant's laboratory testing services.

48. Defendant invited physicians who could direct business to Defendant to participate in a study, sponsored by Defendant, called: "Determination of the Accuracy of PCA3*Plus* Urine Assay for the Detection of Prostate Cancer."

49. The PCA3 gene is a noncoding segment of mRNA located on chromosome 9. The gene is over-expressed by prostate cancer cells in comparison with other cells, making it a genetic marker of prostate cancer.

50. Prostate needle biopsies are the current standard of care, but screening for the PCA3 gene has become more popular, and numerous laboratory services companies perform such analyses.

51. Defendant's PCA3*Plus* urine test is, according to Defendant, a test "specific for the detection of prostate cancer."

52. Defendant claimed in letters to physicians that it sought to enroll 12,000 patients in its study of PCA3*Plus*. The patients to be enrolled were those patients already suspected of or at risk of having prostate cancer, and who already would be coming into physicians' offices for prostate needle biopsies, the standard of care.

53. Defendant induced physicians to participate in this study by paying physicians $100 per patient enrolled in the study. Defendant told physicians that the only requirements were a collection, from patients already coming in for prostate needle biopsies, of a small urine sample (20-30ml), and completion of a short information sheet and consent form. This entire process would take an average physician no more than ten minutes.

54. Importantly, Defendant also required that physicians send both the needle biopsy and the urine collection to Defendant for analysis. As Defendant stated: the needle biopsies "must be sent to Bostwick Laboratories for processing and diagnosis." Absent Defendant's inducement, physicians were free to send patients' needle biopsies to any of a number of laboratories. Defendant's scheme, however, ensured that all of the needle biopsies would come to Defendant.

55. Defendant's $100 per patient payment to participating physicians offered a fantastic return on investment for Defendant. For each $100 that Defendant spent, Defendant received *both* a needle biopsy and a urine sample for each patient. Defendant would then analyze *both* samples and bill Government payors for *both* analyses.

56. Defendant received from Government payors over $1000 for each needle biopsy analysis and $150 for each PCA3*Plus* test – a test that would not have been performed but for Defendant's study.

57. Upon information and belief, Defendant's unlawful kickbacks caused many physicians to send needle biopsies for analysis to Defendant instead of to Defendant's competitors.

58. Upon information and belief, Defendant's unlawful kickbacks caused some physicians to perform needle biopsies that were not medically necessary.

59. Absent Defendant's unlawful kickbacks, many of the needle biopsy analyses that Defendant performed would have been performed by Defendant's competitors, or not at all as they were not medically necessary. For those patients, Defendant would not have been able to bill for the needle biopsy tests nor for the unnecessary PCA3*Plus* tests.

60. Later, Defendant decided to double the amount that it was paying physicians – from $100 to $200 – for the same amount of (non)work.

61. Defendant's Pathology Sales Representative John Chamberlin ("Chamberlin") told Relator that Relator could enroll as many patients as he wanted in the trial, belying Defendant's proffered goal of 12,000 participants and calling into question the methodology of the overall trial.

62. Chamberlin's sales pitch to Relator blatantly connected participation in the purported clinical trial to increase revenue for Relator's office: Chamberlin told Relator that becoming involved in the purported clinical trial "would be a good revenue source for [Relator's] office."

63. Chamberlin also informed Relator that a competing urologist, Dr. Jed Kaminetsky was enrolling at least ten (10) patients per week in the purported clinical trial, and that "he is very satisfied with the revenue stream."

64. On every occasion in which Defendant caused a physician or other heath care professional to be induced by Defendant through means of improper kickbacks to order or send to Defendant needle biopsies or urine samples for PCA3*Plus* testing, and where Defendant later sought

reimbursement for that laboratory testing from Government-funded health programs, a false claim was submitted in violation of the FCA.

65. On information and belief, Defendant engaged, on a nationwide basis, in the practice of providing monetary kickbacks to physicians in exchange for those physicians sending specimens to Defendant for analysis. As Defendant states: "[Bostwick] receives tissue samples from thousands of urologists across the county for processing and diagnosis."

66. Because the needle biopsy tests and the PCA3*Plus* tests were induced by Defendant's unlawful kickback, the entire amount that Defendant billed for such tests are violations of the FCA.

67. Defendant's monetary kickbacks violate the Anti-Kickback Statute and the Stark Law. *See* 42 U.S.C. § 1320a-7b(b); 42 U.S.C. § 1395nn(a)(1), (g)(1).

68. On every occasion in which Defendant or another entity sought reimbursement from a Government-funded health programs for a needle biopsy or *PCA3Plus* urine analysis induced by Defendant's unlawful monetary kickbacks, Defendant knew, or acted in reckless disregard, that a false claim was being submitted, and therefore caused that false claim to be submitted, and is itself liable for such false claim.

2. False Billing for PCA3*Plus* Purported Clinical Trial

69. Defendant billed Government payors for both the needle biopsy and PCA3*Plus* analyses. As Defendant stated, "The study subject's heath insurance will be billed for the urine PCA3Plus test *and* the prostate needle biopsy." (emphasis added) This was true even though, as Defendant admits, "The needle biopsy is diagnosed as a standard of care procedure[.]"

70. Even if Defendant had not paid kickbacks, and regardless of whether the PCA3*Plus* clinical trial was a sham intended only to drive business to Defendant or a legitimate clinical trial, Defendant should not have billed Government payors for PCA3*Plus* testing conducted pursuant to

the trial because the purported clinical trials run afoul of the regulations in the previously discussed NCD. Specifically:

(a) The investigational item or service – here, the PCA3*Plus* would not have been covered outside of the clinical trial because it was not medically necessary (the needle biopsy is the standard of care and the only test that would have been performed), and therefore was not a "routine cost";

(b) the PCA3*Plus* test was performed "solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan)" – the NCD's example about unnecessary testing is especially relevant here – and therefore was not a "routine cost"; and

(c) on information and belief, sponsors of clinical trials, e.g., drug manufacturers testing a new drug, customarily provide the product being tested "free of charge for any enrollee in the trial," rendering the PCA3*Plus* test an "[i]tem[] and service[]customarily provided by the research sponsors free of charge for any enrollee in the trial" and therefore not a "routine cost."

71. On every occasion in which Defendant or another entity sought reimbursement from a Government-funded health programs for a *PCA3Plus* urine analysis collected as a part of Defendant's sponsored clinical trial, Defendant knew, or acted in reckless disregard, that a false claim was being submitted, and therefore caused that false claim to be submitted, and is itself liable for such false claim.

72. Defendant's scheme is further evident from Defendant's policy of indemnifying patients and physicians if certain payors audited claims and refused to pay for Defendant's clinical trial testing. "If the PCA3Plus test is not covered by the insurance company, the study sponsor will cover the fee for the testing," wrote Bostwick Executive Vice President for Clinical Research Krystuna

Drewnowska, seeking to assure physicians that neither they nor their patients would be liable if Defendant's reimbursement scheme fell through, and that Defendant would carry the risk of reimbursement rejections.

3. Kickbacks for Uro*FISH* Clinical Trial

73. Defendant executed a similar scheme under the guise of its Uro*FISH* clinical trial.

74. In 2008, or earlier, the exact date being unknown to Relator, Defendant began offering payments to physicians to utilize and over-utilize Defendant's laboratory testing services.

75. Defendant invited physicians who could direct business to Defendant to participate in study, sponsored by Defendant, called: "Determination of the Accuracy of Uro*FISH* Urine Assay for the Detection of Bladder Cancer."

76. Urine cytology and UroVysion testing prior to cystoscopy are the current standard of care for bladder cancer and numerous laboratory services companies perform such analyses.

77. Defendant's Uro*FISH* urine test is a new test for bladder cancer.

78. The patients to be enrolled were those patients already suspected of or at risk of having bladder cancer, and who already would be coming into physicians' offices for urine cytology and UroVysion testing, the standard of care.

79. Defendant induced physicians to participate in this study by paying physicians $100 per patient enrolled in the study. Defendant told physicians that the only requirements were a collection, from patients already coming in for urine cytology and UroVysion testing, of a urine sample, and completion of a short information sheet and consent form. This entire process would take an average physician no more than 10 minutes.

80. Importantly, Defendant also required that physicians send both the urine cytology and UroVysion testing to Defendant for analysis. Absent Defendant's inducement, physicians were free

to send urine cytology and UroVysion testing to any of a number of laboratories. Defendant's scheme, however, ensured that all of the urine cytology and UroVysion testing would come to Defendant.

81. Defendant's $100 per patient payment to participating physicians offered a fantastic return on investment for Defendant. For each $100 that Defendant spent, Defendant received, analyzed, and billed Government payors for urine cytology and UroVysion testing.

82. Defendant received from Government payors approximately $100 for each urine cytology analysis and approximately $800 for each UroVysion testing analysis.

83. Upon information and belief, Defendant's unlawful kickbacks caused many physicians to send urine cytology and UroVysion testing for analysis to Defendant instead of to Defendant's competitors.

84. Upon information and belief, Defendant's unlawful kickbacks caused some physicians to perform urine cytology and UroVysion testing that were not medically necessary.

85. Absent Defendant's unlawful kickbacks, many of the urine cytology and UroVysion testing analyses that Defendant performed would have been performed by Defendant's competitors, or not at all as they were not medically necessary. For those patients, Defendant would not have been able to bill for the urine cytology and UroVysion testing.

86. Later, Defendant decided to double the amount that it was paying physicians – from $100 to $200 – for the same amount of (non)work.

87. On every occasion in which Defendant caused a physician or other heath care professional to be induced by Defendant through means of improper kickbacks to order or send to Defendant urine cytology and UroVysion testing, and where Defendant later sought reimbursement

for that laboratory testing from Government-funded health programs, a false claim was submitted in violation of the FCA.

88. On information and belief, Defendant engaged, on a nationwide basis, in the practice of providing monetary kickbacks to physicians in exchange for those physicians sending specimens to Defendant for analysis.

89. Because the urine cytology and UroVysion testing were induced by Defendant's unlawful kickback, the entire amount that Defendant billed for such tests are violations of the FCA.

90. Defendant's monetary kickbacks violate the Anti-Kickback Statute and the Stark Law. *See* 42 U.S.C. § 1320a-7b(b); 42 U.S.C. § 1395nn(a)(1), (g)(1).

91. On every occasion in which Defendant or another entity sought reimbursement from a Government-funded health programs for urine cytology or UroVysion testing analysis induced by Defendant's unlawful monetary kickbacks, Defendant knew, or acted in reckless disregard, that a false claim was being submitted, and therefore caused that false claim to be submitted, and is itself liable for such false claim.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(False Claims Act: Presentation Of False Claims)
(31 U.S.C. § 3729(a)(1))

92. Relator repeats and incorporates by reference the allegations contained above as it if fully set forth herein.

93. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein Defendant has knowingly presented or caused to be presented to officers or employees of the United State Government false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1).

SECOND CAUSE OF ACTION

(False Claims Act: Making Or Using False
Record Or Statement to Cause Claim To Be Paid)
(31 U.S.C. § 3729(a)(2)

94. Relator repeats and incorporates by reference the allegations contained above as if fully set forth herein.

95. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, Defendant has knowingly made, used, or caused to be made or used false or fraudulent records or statements to get false or fraudulent claims paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(2).

THIRD CAUSE OF ACTION

(False Claims Act: Making Or Using False
Record Or Statement to Avoid An Obligation To Refund)
(31 U.S.C. § 3729(a)(7)

96. Relator repeats and incorporates by reference the allegations contained above as if fully set forth herein

97. As more particularly set forth in the foregoing paragraphs, by virtue of the acts and alleged herein, Defendant knowingly made, used or caused to be made or used false or fraudulent records or statements to conceal, avoid or decrease an obligation to pay or transmit money or property to the United States of America.

FOURTH CAUSE OF ACTION

(Arkansas Medicaid Fraud False Claims Act)
(Ark. Code Ann. §20-77-901)

98. Relator re-alleges and incorporates by reference the allegations made above.

99. This is a claim for treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act. Ark. Code Ann. § 20-77-901.

100. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant has knowingly caused to be presented to the Arkansas Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

101. The Arkansas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

102. By reasons of these payments, the Arkansas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

FIFTH CAUSE OF ACTION

(California False Claims Act)
(Cal. Gov't Code § 12651, *et seq.*)

103. Relator re-alleges and incorporates by reference the allegations above.

104. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code 12651, *et seq.*

105. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the California Medicaid Program (*i.e.*, Medi-Cal) false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

106. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

107. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

SIXTH CAUSE OF ACTION

(Delaware False Claims Act)
(Del. Code Ann. tit. 6, § 1201, *et seq.*)

108. Relator re-alleges and incorporates by reference the allegations made above

109. This is a claim for treble damages and civil penalties under the Delaware False Claims Act. Code Ann. tit. 6, § 1201, *et seq.*

110. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Delaware Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

111. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

112. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

SEVENTH CAUSE OF ACTION

(Florida False Claims Act)
(Fla. Stat. Ann. § 68.081, *et seq.*)

113. Relator re-alleges and incorporates by reference the allegations made above.

114. This is a claim for treble damages and civil penalties under the Florida False Claims Act. Fla. Stat. Ann. § 68.081, *et seq.*

115. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Florida Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

116. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

117. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

EIGHT CAUSE OF ACTION

(Hawaii False Claims Act)
(Haw. Rev. Stat.. § 661.22, *et seq.*)

118. Relator re-alleges and incorporates by reference the allegations made above.

119. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act. Haw. Rev. Stat. § 661.22, *et seq.*

120. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Hawaii Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

121. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

122. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

NINTH CAUSE OF ACTION

(Illinois Whistleblower Reward and Protection Act)
(740 Ill. Comp. Stat. 175/1, *et seq.*)

123. Relator re-alleges and incorporates by reference the allegations made above.

124. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act. 740 Ill. Comp. Stat. 175/1, *et seq.*

125. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Illinois Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

126. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

127. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TENTH CAUSE OF ACTION

(Indiana False Claims & Whistleblower Protection Act)
(Ind. Code 5-11-5.5)

128. Relator re-alleges and incorporates by reference the allegations made above.

129. This is a claim for treble damages and civil penalties under the Indiana False Claims & Whistleblower Protection Act. Ind. Code 5-11-5.5.

130. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Illinois Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

131. The Indiana Medicaid Program, unaware of falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

132. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

ELEVENTH CAUSE OF ACTION

(Louisiana Medical Assistance Programs Integrity Law)
(La. Rev. Stat. Ann § 46:439.1, *et seq.*)

133. Relator re-alleges and incorporates by reference the allegations made above.

134. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law. La. Rev. Stat. Ann. § 46:439.1, *et seq.*

135. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Louisiana Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

136. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

137. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWELFTH CAUSE OF ACTION

(Massachusetts False Claims Act)
(Mass. Ann. Laws ch. 12, §5(A)-(O))

138. Relator re-alleges and incorporates by reference the allegations made above.

139. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act. Mass. Ann. Laws Ch. 12 §5(A)-(O).

140. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

141. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

142. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

THIRTEENTH CAUSE OF ACTION

(Nevada False Claims Act)

(Nev. Rev. Stat. § 357.010, *et seq.*)

143. Relator re-alleges and incorporates by reference the allegations made above.

144. This is a claim for treble damages and civil penalties under the Nevada False Claims Act. Nev. Rev. Stat. § 357.010, *et seq.*

145. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Nevada Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

146. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

147. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

FOURTEENTH CAUSE OF ACTION

(New Hampshire Medicaid Fraud and False Claims)
(N.H. Rev. Stat. Ann. §167:61, *et seq.*)

148. Relator re-alleges and incorporates by reference the allegations made above.

149. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law. N.H. Rev. Stat. Ann. §167:61, *et seq.*

150. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

151. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

152. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

FIFTEENTH CAUSE OF ACTION

(New Mexico Medicaid False Claims Act)
(N.M. Stat. Ann. § 27-14-1, *et seq.*)

153. Relator re-alleges and incorporates by reference the allegations made above.

154. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act. N.M. Stat. Ann. § 27-14-1, *et seq.*

155. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Mexico Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

156. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

SIXTEENTH CAUSE OF ACTION

(New York False Claims Act)
(N.Y. Stat. Ann. Ch. 56, Art. XIII, § 187, *et seq.*)

157. Relator re-alleges and incorporates by reference the allegations made above.

158. This is a claim for treble damages and civil penalties under the New York False Claims Act. N.Y. Stat. Ann. Ch. 56, Art. XIII, § 187, *et seq.*

159. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New York Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

160. New York, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

161. By reason of these payments, New York has been damaged, and continues to be damaged in a substantial amount.

SEVENTEENTH CAUSE OF ACTION

(Tennessee Medicaid False Claims Act)
(Tenn. Code Ann. § 71-5-181, *et seq.*)

162. Relator re-alleges and incorporates by reference the allegations made above.

163. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, and Tennessee False Claims Act. Tenn. Code Ann. § 71-5-181, *et seq.*

164. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Tennessee Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

165. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

166. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

EIGHTEENTH CAUSE OF ACTION

(Texas Medicaid Fraud Prevention Act)
(Tex. Hum. Res. Code Ann. § 36.001, *et seq.*)

167. Relator re-alleges and incorporates by reference the allegations made above.

168. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act. Tex. Hum. Res. Code Ann. § 36.001, *et seq.*

169. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Texas Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

170. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

171. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

NINETEENTH CAUSE OF ACTION

(Utah False Claim Act)
(Utah Code Ann. § 26-20, *et seq.*)

172. Relator re-alleges and incorporates by reference the allegations made above.

173. This is a claim for treble damages and civil penalties under the Utah False Claims Act. Utah Code Ann. § 26-20, *et seq.*

174. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Utah Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

175. The Utah Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

176. By reason of these payments, the Utah Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTIETH CAUSE OF ACTION

(Virginia Fraud Against Taxpayers Act)
(Va. Code Ann. § 8.01-216, *et seq.*)

177. Relator re-alleges and incorporates by reference the allegations made above.

178. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act. Va. Code Ann. § 8.01-216, *et seq.*

179. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Virginia Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

180. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

181. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-FIRST CAUSE OF ACTION

(District of Columbia False Claims Act)
(D.C. Code § 2-308.03 *et seq.*)

182. Relator re-alleges and incorporates by reference the allegations made above.

183. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act. D.C. Code § 2-308.03 *et seq.*

184. By virtue of the kickbacks and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims, and used false or fraudulent records to accomplish this purpose.

185. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

186. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

WHEREFORE, Relator Robert Gluck requests that judgment be entered against the Defendant, ordering that:

(a) Defendant ceases and desists from violating the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and the state false claims acts;

(b) Defendant pay not less than $5,500 and not more that $11,000 for each violation of 31 U.S.C. §3729, plus three times the amount of damages the United States has sustained because of Defendant's actions, plus the appropriate amount to the Certain States under similar provisions of the state false claims acts;

(c) Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state false claims acts;

(d) Relator be awarded reimbursement of all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state false claims acts;

(e) Defendant be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

(f) Defendant disgorge all sums by which it has been enriched unjustly by its wrongful conduct; and

(g) The United States, the Certain States and Relator Robert Gluck recover such other relief as the Court deems just and proper.

Filed Under Seal Pursuant to
31 U.S.C. § 3730(b)(2)

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator Robert Gluck hereby demands a trial by jury.

Dated: September 25, 2009

KAPLAN, FOX & KILSHEIMER, LLP

By: _____
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